California State Board of Pharmacy
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Phone (916) 574-7900
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www.pharmacy.ca.gov

STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
ARNOLD SCHWARZENEGGER, GOVERNOR

Clear Print

HOSPITAL PHARMACY SELF-ASSESSMENT

The California Code of Regulations section 1715 requires the pharmacist-in-charge of each pharmacy licensed under section 4037 or 4029 of the Business and Professions Code to complete a self-assessment of the pharmacy's compliance with federal and state pharmacy law. **The assessment shall be performed before July 1 of every odd-numbered year. The pharmacist-in-charge must also complete a self-assessment within 30 days whenever (1) a new pharmacy permit has been issued, or (2) there is a change in the pharmacist-in-charge. The primary purpose of the self-assessment is to promote compliance through self-examination and education.**

The self-assessment must be competed in entirety and may be completed online, printed and retained in the pharmacy. Do not copy a previous assessment.

Note: If dispensing prescriptions for outpatient use, a Community Pharmacy Self-Assessment must be completed also.

Each self-assessment must be kept on file in the pharmacy for three years after it is performed.

Pharmacy Name: _____

Address: _____ Phone: _____

Ownership: Sole Owner ☐ Partnership ☐ Corporation ☐ LLC ☐
Non-Licensed Owner ☐ Other (please specify) ☐ _____

Permit #: _____ Exp. Date:_____ Other Permit #: _____ Exp. Date: _____

Licensed Sterile Compounding Permit # _____ or Accredited by: _____

DEA Registration #: _____ Exp. Date: _____ Date of DEA Inventory: _____

Hours: *Daily*_____ *Sat*_____ *Sun.* _____ *24 Hours* _____

PIC: _____ RPH # _____ Exp. Date: _____

Pharmacy staff (pharmacists, interns, technicians):

1. _____ RPH # _____ Exp. Date: _____

2. _____ RPH # _____ Exp. Date: _____

3. _____ RPH # _____ Exp. Date: _____

Pharmacy Staff (continued): (Please use an additional sheet if necessary)

4. _____ RPH # _____ Exp. Date: _____

5. _____ RPH # _____ Exp. Date: _____

6. _____ RPH # _____ Exp. Date: _____

7. _____ RPH # _____ Exp. Date: _____

8. _____ RPH # _____ Exp. Date: _____

9. _____ INT # _____ Exp. Date: _____

10. _____ INT # _____ Exp. Date: _____

11. _____ INT # _____ Exp. Date: _____

12. _____ TCH # _____ Exp. Date: _____

13. _____ TCH # _____ Exp. Date: _____

14. _____ TCH # _____ Exp. Date: _____

15. _____ TCH # _____ Exp. Date: _____

16. _____ TCH # _____ Exp. Date: _____

17. _____ TCH # _____ Exp. Date: _____

18. _____ TCH # _____ Exp. Date: _____

PIC Initials _____

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HOSPITAL SELF-ASSESSMENT

All references to the California Code of Regulations (CCR) are Title 16 unless otherwise noted.

Please mark the appropriate box for each question. If "NO," enter an explanation on "CORRECTIVE ACTION or ACTION PLAN" lines below. If more space is needed, you may add additional sheets.

1. Pharmacy

Yes	No	N/A	
☐	☐	☐	The pharmacy is secure and has provisions for effective control against the theft of dangerous drugs and devices. (B&PC 4117, CCR 1714)
☐	☐	☐	The pharmacy maintains "night stock" medications which are accessible without entering the pharmacy during hours when the pharmacy is closed, and the pharmacist is not available. Access is limited to designated registered nurses. (22 CCR 70263[n])
☐	☐	☐	The pharmacy is of sufficient size and has an unobstructed area to accommodate the safe practice of pharmacy. (CCR 1714)
☐	☐	☐	The pharmacy premises**,** fixtures**,** and equipment are maintained in a clean and orderly condition. (CCR 1714)
☐	☐	☐	The pharmacy sink has hot and cold running water. (CCR 1714)
☐	☐	☐	The pharmacy has a readily accessible restroom. (CCR 1714)
☐	☐	☐	The original board-issued pharmacy license and the current renewal are posted where they may be clearly read by the purchasing public. (B&PC 4032, 4058)
☐	☐	☐	Pharmacists, interns, pharmacy technicians, and pharmacy technician trainees wear nametags, in 18-point type, that contain their name and license status. (B&PC 680, B&PC 4115.5[e], CCR 1793.7[d])
☐	☐	☐	Does the pharmacy compound sterile injectable drugs? (If yes, complete section 24 – "Compounding Sterile Injectable Drugs")

CORRECTIVE ACTION OR ACTION PLAN: _____

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2. Nursing Stations

Yes No N/A

☐☐☐ Adequate space is available at ward or nursing station for the storage of drugs and preparation of medication doses. All such spaces and areas can be locked and are accessible to authorized personnel only. (22 CCR 70269)

☐☐☐ The pharmacist is responsible for the monthly inspections of all floor stock and drugs maintained in nursing stations. Any irregularities are reported to the director of nursing services, and as required by hospital policy. (22 CCR 70263[q][10])

CORRECTIVE ACTION OR ACTION PLAN: _____

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3. Delivery of Drugs

Yes No N/A

☐☐☐ Delivery to the pharmacy of dangerous drugs and dangerous devices are only delivered to the licensed premise and signed for and received by a pharmacist. (B&PC 4059.5[a])

☐☐☐ Deliveries to a hospital pharmacy may be made to a central receiving location within the hospital. However, the dangerous drugs or dangerous devices shall be delivered to the licensed pharmacy premise within one working day following receipt by the hospital, and the pharmacist on duty at that time shall immediately inventory the drugs or devices. (B&PC 4059.5[c])

A pharmacy may take delivery of dangerous drugs and dangerous devices when the pharmacy is closed and no pharmacist is on duty if all of the following requirements are met (B&PC 4059.5[f]):

☐☐☐ The drugs are placed in a secure storage facility in the same building as the pharmacy (B&PC 4059.5[f][1]);

☐☐☐ Only the pharmacist-in-charge or a pharmacist designated by the pharmacist-in-charge has access to the secure storage facility after dangerous drugs or dangerous devices have been delivered (B&PC 4059.5[f][2]);

☐☐☐ The secure storage facility has a means of indicating whether it has been entered after dangerous drugs or dangerous devices have been delivered (B&PC 4059.5[f][3]);

☐☐☐ The pharmacy maintains written policies and procedures for the delivery of dangerous drugs and dangerous devices to a secure storage facility (B&PC 4059.5[f][4]); and

☐☐☐ The agent delivering dangerous drugs and dangerous devices pursuant to this subdivision leaves documents indicating the name and amount of each dangerous drug or dangerous device delivered in the secure storage facility. The pharmacy shall be responsible for the dangerous drugs and dangerous devices delivered to the secure storage facility. The pharmacy shall also be responsible for obtaining and maintaining records relating to the delivery of dangerous drugs and dangerous devices to a secure storage facility. (B&PC 4059.5[f][5])

CORRECTIVE ACTION OR ACTION PLAN: _____

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4. Drug Stock

Yes No N/A

☐☐☐ The drug stock is clean, orderly, properly stored, properly labeled and in-date. (B&PC 4342, H&SC 111255, 22 CCR 70263[q])

☐☐☐ All ward/floor drug stock and drug supplies that are maintained for access when the pharmacist is not available are properly labeled and stored. (22 CCR 70263[n])

☐☐☐ Preferentially priced drugs are furnished solely or predominately to inpatients in accordance with provisions of the Nonprofit Institutions Act (15 USC 13c). Such drugs also may be dispensed pursuant to prescriptions for inpatients at the time of discharge, for employees of the hospital, or on an emergency basis for a walk-in customer (provided that sales to walk-ins do not exceed one percent of the pharmacy's total prescription sales). (B&PC 4380, CCR 1710)

CORRECTIVE ACTION OR ACTION PLAN: _____

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5. Pharmacist-in-Charge (PIC)

Yes No N/A

☐☐☐ The pharmacy has a PIC who is responsible for the daily operation of the pharmacy. (B&PC 4101, 4113, 4305, 4330, CCR 1709, 1709.1)

☐☐☐ The PIC has adequate authority to assure the pharmacy's compliance with laws governing the operation of a pharmacy (CCR 1709.2[b])

☐☐☐ Is the PIC in charge of another pharmacy?

☐☐☐ If yes, the pharmacies are within 50 driving distance miles of each other. (CCR 1709.1[c])

If yes, name of other pharmacy _____

☐☐☐ Any change of PIC is reported by the pharmacy and the departing PIC to the board in writing within 30 days. (B&PC 4101, 4330)

☐☐☐ Is the PIC serving concurrently as the exemptee-in-charge for a wholesaler or veterinary food-animal retailer? (CCR 1709[c])

If yes, name the wholesaler or veterinary food-animal retailer. _____

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

6. Duties of a Pharmacist

Yes No N/A

☐☐☐ Within the scope of the inpatient pharmacy service, the pharmacist receives a chart order for an inpatient; identifies, evaluates and interprets the chart order; reviews patient's drug regimen and interprets the clinical data in the patient's medication record; consults with any prescriber, nurse or health care professional; calculates drug doses; supervises the packaging of drugs and checks the packaging procedures and products upon completion; is responsible for all activities of pharmacy technicians, interns and clerks related to the furnishing of drugs to ensure that all such activities are performed completely, safely and without risk of harm to patients; performs any other duty which federal or state law or regulation authorizes only a registered pharmacist to perform; and performs all functions which require professional judgment. (B&PC 4051, CCR 1793.1)

☐☐☐ Pharmacists in a licensed health care facility who are performing the following functions are doing so in accordance with the hospital's policies, procedures and protocols which have been developed by health professionals including physicians, pharmacists, and registered nurses, with the concurrence of the facility administrator; ordering or performing routine drug therapy-related patient assessment procedures; ordering drug therapy-related laboratory tests; administering drugs or biologicals by injection; initiating or adjusting the drug regimen of a patient, and/or performing moderate or waived laboratory tests. Prior to performing any of these functions, the pharmacist must have either (1) successfully completed clinical residency training or (2) demonstrated clinical experience in direct patient care delivery as specified in B&PC section 4052(b). (B&PC 4027, 4051, 4052)

CORRECTIVE ACTION OR ACTION PLAN: _____

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7. Duties of an Intern Pharmacist

Yes No N/A

☐☐☐ Intern pharmacists are performing all the functions of a pharmacist only under the direct supervision of a pharmacist, and the pharmacist is supervising no more than **two interns** at any one time. (B&PC 4114, CCR 1726, 1727)

☐☐☐ All prescriptions filled or refilled by an intern are initialed by a pharmacist prior to dispensing. (CCR 1717[b][1])

CORRECTIVE ACTION OR ACTION PLAN: _____

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8. Duties of a Pharmacy Technician

Yes No N/A

☐☐☐ Registered pharmacy technicians are performing packaging, manipulative, repetitive, or other nondiscretionary tasks related to the furnishing of drugs, while assisting and under the direct supervision and control of a pharmacist. (B&PC 4038, 4115, CCR 1793.2)

☐☐☐ The ratio for technicians performing the tasks above, related to the furnishing of drugs to inpatients, does not exceed one pharmacist on duty for two technicians on duty. However, when prescriptions are dispensed to discharge patients with only one pharmacist, there is no more than one technician performing the tasks as defined in B&PC 4115(a). The ratio of pharmacy technicians performing those tasks for additional pharmacists does not exceed 2:1. (B&PC 4038, 4115, CCR 1793.7[f])

Yes No N/A

☐☐☐ Any function performed by a technician in connection with the dispensing of a prescription or chart order, including repackaging from bulk and storage of pharmaceuticals is verified and documented in writing by a pharmacist. (CCR 1793.7)

☐☐☐ A pharmacy technician or pharmacy technician trainee wears identification, in 18-point type that identifies him or her self as a pharmacy technician or pharmacy technician trainee. (B&PC 680, B&PC 4115.5[e], CCR 1793.7[d])

☐☐☐ The pharmacy has a job description for the pharmacy technician and written policies and procedures to ensure compliance with the technician requirements. (CCR 1793.7)

☐☐☐ The ratio is no less than one pharmacist to two technicians. (B&PC 4115[g], CCR 1793.7)

CORRECTIVE ACTION OR ACTION PLAN: _____

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9. Duties of Non-Licensed Personnel

Yes No N/A

☐☐☐ A non-licensed person (clerk/typist) is permitted to type a prescription label or otherwise enter prescription information into a computer record system, and at the direction of a pharmacist, may request and receive refill authorization. (B&P 4007,CCR 1793.3)

☐☐☐ The number of non-licensed personnel supervised by each pharmacist does not interfere with the effective performance of the pharmacist's responsibilities under the Pharmacy Law. (CCR 1793.3[b])

CORRECTIVE ACTION OR ACTION PLAN: _____

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PHARMACY PRACTICE

10. Pharmaceutical Service Requirements

The pharmacy complies with the requirements of 22 CCR 70263, addressing the following areas in written policies and procedures:

Yes No N/A

☐☐☐ Basic information concerning investigational drugs and adverse drug reactions;

☐☐☐ Repackaging and compounding records;

☐☐☐ Physician orders;

☐☐☐ Wards, nursing stations and night stock medications;

☐☐☐ Drugs brought into the facility by patients for storage or use;

☐☐☐ Bedside medications;

Yes No N/A

☐☐☐ Emergency drug supply;

☐☐☐ Pass medications;

☐☐☐ Inspection of ward stock, nursing stations and night lockers no less frequently than every 30-days\\Outdated drugs;

☐☐☐ Routine distribution of inpatient medications;

☐☐☐ Preparation, labeling and distribution of IV admixtures and cytotoxic agents;

☐☐☐ Handling of medication when pharmacist not on duty; and

☐☐☐ Use of electronic image and data order transmissions.

The pharmacy complies with the requirements of 22 CCR 70263, addressing the following areas:

☐☐☐ Destruction of controlled substances; and

☐☐☐ Development and maintenance of the hospital's formulary. (22 CCR 70263, CCR 1751, 1751.8)

CORRECTIVE ACTION OR ACTION PLAN: _____

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11. Medication/Chart Order

Yes No N/A

☐☐☐ The pharmacy receives the original, the electronic transmission, or a copy of the medication order. Faxed copies, tele-autograph copies, or transmissions between computers are permissible. (B&PC 4019, 4040, CCR 1717.4)

☐☐☐ The chart or medical record of the patient contains all of the information required by B&PC 4040 and the chart order is signed by the practitioner authorized by law to prescribe drugs if present or, if not present, within a specified time frame not exceeding 48 hours. (B&PC 4040, 22 CCR 70263[g])

☐☐☐ A copy of the chart order is maintained on the premises for three years. (B&PC 4081, 4105, 4333)

CORRECTIVE ACTION OR ACTION PLAN: _____

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12. Labeling and Distribution

Yes No N/A

☐☐☐ Unit dose medication and parenteral admixtures are properly labeled and include the information as required by B&PC 4076, or the information is otherwise readily available at the time of drug administration.(B&PC 4046)

Yes No N/A

☐☐☐ The pharmacist is responsible for the proper labeling, storage and distribution of investigational drugs pursuant to the written order of the investigator. (22 CCR 70263[o]).

☐☐☐ This pharmacy furnishes dangerous drugs in compliance with B&PC 4126.5 only to a patient pursuant to a prescription, a wholesaler from whom the dangerous drugs were purchased, a manufacturer from whom the drugs were purchased, a licensed wholesaler acting as a reverse distributor, another pharmacy to alleviate a temporary shortage with a quantity sufficient to alleviate the temporary shortage, a health care provider authorized to received drugs, or to another pharmacy of common ownership,

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

13. Duration of Drug Therapy

Yes No N/A

☐☐☐ The hospital has policies limiting the duration of drug therapy in the absence of the prescriber's specific indication of duration of drug therapy or under other circumstances recommended by the pharmacy and therapeutics committee or its equivalent and approved by the executive committee of the medical staff. Limitations are established for classes of drugs and/or individual drug entities. (22 CCR 70263[j])

CORRECTIVE ACTION OR ACTION PLAN: _____

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14. Confidentiality of Chart Orders, Prescriptions and Patient Medical Information

Yes No N/A

☐☐☐ Patient information is maintained to safeguard confidentiality. (Civil Code 56 et seq.)

☐☐☐ Patient medical information, all prescriptions (chart orders, patient discharge and employee prescriptions) are confidential and are not disclosed unless authorized by law. (B&PC 4040, CCR 1764)

☐☐☐ Destruction or disposal of patient records preserves the confidentiality of the information contained therein. (Civil Code 56.101)

☐☐☐ The pharmacy ensures electronically transmitted prescriptions (chart orders, discharge patient or employee prescriptions) are received, maintained and transmitted in a secure and confidential manner. (CCR 1717.4)

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

15. Quality Assurance and Medication Errors

Yes No N/A

☐☐☐ Pharmacy has established quality assurance program that documents medication errors attributable, in whole or in part, to the pharmacy or its personnel. (B&PC 4125, CCR 1711)

☐☐☐ Pharmacy quality assurance policies and procedures are maintained in the pharmacy and are immediately retrievable. (CCR 1711[c])

☐☐☐ When a medication error has occurred (drug was administered to or by the patient, or resulted in a clinically significant delay in therapy) the pharmacist communicates with the patient or patient's agent that a medication error has occurred and the steps required to avoid injury or mitigate the error. (CCR 1711[c][2][A], 1711[c][3])

☐☐☐ When a medication error has occurred (drug was administered to or by the patient, or resulted in a clinically significant delay in therapy) the pharmacist communicates to the prescriber that a medication error has occurred. (CCR 1711[c][2][B], 1711[c][3])

☐☐☐ Investigation of pharmacy medication errors is initiated within two business days from the date the medication error is discovered. (CCR 1711[d])

The record for quality assurance review for a medication error contains: (CCR 1711[e])

☐☐☐ Date, location, and participants in the quality assurance review;

☐☐☐ Pertinent data and other information related to the medication error(s) reviewed;

☐☐☐ Findings and determinations;

☐☐☐ Recommended changes to pharmacy policy, procedure, systems or processes, if any.

☐☐☐ The record of the quality assurance review is immediately retrievable in the pharmacy and is maintained in the pharmacy for at least one year from the date it was created. (CCR 1711[f])

☐☐☐ Pharmacists are not deviating from the requirements of a prescription except upon the prior consent of the prescriber, and selection of the drug product is in accordance with B&PC 4073 (generic substitution). (CCR 1716)

CORRECTIVE ACTION OR ACTION PLAN: _____

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16. Record Keeping Requirements

Yes No N/A

☐☐☐ A completed biennial pharmacy self -assessment is on file in the pharmacy and maintained for three years. (CCR 1715)

☐☐☐ All drug acquisition and disposition records (complete accountability) are maintained for at least three years. These records include:

Yes	No	N/A	
☐	☐	☐	Prescription records (CCR 4081[a])
☐	☐	☐	Purchase Invoices for all prescription drugs (4081[b])
☐	☐	☐	Biennial controlled substances inventory (21 CFR 1304.11)
☐	☐	☐	U.S. Official Order Forms (DEA Form-222) (21 CFR 1305.13)
☐	☐	☐	Power of Attorney for completion of DEA 222 forms (21 CFR 1305.07)
☐	☐	☐	Theft and Loss Reports (DEA Form 106) (21 CFR 1301.74[c])
☐	☐	☐	Record documenting return of drugs to wholesaler or manufacturer (CCR 4081)
☐	☐	☐	Record documenting transfers or sales to other pharmacies and prescribers (B&PC 4059, 4081, 4105, 4332, CCR 1718)
☐	☐	☐	Transfers or sales to other pharmacies and prescribers do not exceed five percent of the pharmacy's total annual purchases of dangerous drugs or devices. If more than five percent, registration with the board as a wholesaler has been obtained. (21CFR 1307.11, Prescription Drug Marketing Act [PDMA] [Pub. L. 100-293, Apr. 22, 1988] 503, B&PC 4160)
☐	☐	☐	If sales or distributions of controlled substances to other hospitals, pharmacies, or prescribers exceed five percent of the total number of controlled substances dosage units (that are furnished to the inpatients or dispensed on prescriptions to discharge patients or employees) per calendar year, the following have been obtained: a separate DEA distributor registration and a wholesaler's permit from the board. (21 CFR 1307.11, PDMA 503, B&PC 4160)
☐	☐	☐	A controlled substances inventory is completed biennially (every two years). Date completed: _____ (21 CFR 1304.11)
☐	☐	☐	Separate Schedule II records are maintained. This includes triplicate prescriptions, invoices, US official order forms and inventory records. (21 CFR 1304.04)
☐	☐	☐	Inventories and records for Schedule III-V controlled substances are filed separately or maintained in a readily retrievable manner that distinguishes them from other ordinary business records. (21 CFR 1304.04)
☐	☐	☐	DEA Forms-222 are properly executed. (21 CFR 1305.09)
☐	☐	☐	When the pharmacy distributes Schedule II controlled substances to other DEA registrants, Copy 2 of the DEA Form-222, properly completed, are submitted at the end of each month to the DEA Regional Office. (21 CFR 1309.09)
☐	☐	☐	Any controlled substances drug loss is reported upon discovery to the DEA and to the Board of Pharmacy within 30 days. (21 CFR 1301.74[c], CCR 1715.6)

Yes No N/A

☐☐☐ Records stored off-site (only for pharmacies who have obtained a waiver from the Board of Pharmacy to store records off-site) are secure and retrievable within two business days. Records for non-controlled substances are maintained on the licensed premises for at least one year from the date of dispensing. Controlled substances are maintained on the licensed premises for at least two years from the date of dispensing (CCR 1707)

☐☐☐ Do pharmacy staff hand initial prescription records and prescription labels, OR

☐☐☐ Does the pharmacy comply with the requirement for a pharmacist to initial or sign a prescription record or prescription label by recording the identity of the reviewing pharmacist in a computer system by a secure means. This computer does not permit the record to be altered after made and the record of the pharmacist's identity made in the computer system is immediately retrievable in the pharmacy. (CCR1712)

CORRECTIVE ACTION OR ACTION PLAN: _____

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17. After-Hours Supply of Medication

Yes No N/A

☐☐☐ The pharmacy maintains a record of the drugs taken from the after-hours supply of medications and the pharmacist is notified of such use. The record includes the name and strength of the drug, the amount taken, the date and time, the name of the patient to whom the drug was administered and the signature of the registered nurse. (22 CCR 70263[n])

CORRECTIVE ACTION OR ACTION PLAN: _____

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18. Drug Supplies for Use in Medical Emergencies

Yes No N/A

☐☐☐ A supply of drugs for use in medical emergencies only is immediately available at each nursing unit or service area as required. (22 CCR 70263[f])

☐☐☐ Written policies and procedures have been developed that establish the contents of the supply, procedures for use, restocking and sealing of the emergency drug supply. (22 CCR 70263[f][1])

☐☐☐ The emergency drug supply is stored in a clearly marked portable container which is sealed by the pharmacist in such a manner that a seal must be broken to gain access to the drugs. The contents of the container are listed on the outside cover and include the earliest expiration date of any drugs within. (Title 22 CCR 70263[f][2])

☐☐☐ The pharmacist is responsible for inspection of the drug supply at periodic intervals (no less frequently than every 30 days) specified in the writ ten policies. Records of the inspection are kept for at least three years. (22 CCR 70263[f][3])

CORRECTIVE ACTION OR ACTION PLAN: _____

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19. Schedule II-V Controlled Substances Floor Stock Distribution Records

Yes No N/A

☐☐☐ Records for the distribution of Schedule II-V controlled substances floor stock are open to inspection by authorized officers of the law and are preserved for at least three years from the date of making. (B&PC 4081)

CORRECTIVE ACTION OR ACTION PLAN: _____

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20. Emergency Room Dispensing

A prescriber may dispense a dangerous drug, including a controlled substance, to an emergency room patient if all of the following apply (B&PC 4068[a]):

Yes No N/A

☐☐☐ The hospital pharmacy is closed and there is no pharmacist available in the hospital;

☐☐☐ The dangerous drug is acquired by the hospital pharmacy;

☐☐☐ The dispensing information is recorded and provided to the pharmacy when the pharmacy reopens;

☐☐☐ The hospital pharmacy retains the dispensing information and, if the drug is a schedule II or schedule III controlled substance, reports the dispensing information to the Department of Justice pursuant to Section 11165 of the Health and Safety Code;

☐☐☐ The prescriber determines that it is in the best interest of the patient that a particular drug regimen be immediately commenced or continued, and the prescriber reasonably believes that a pharmacy located outside the hospital is not available and accessible at the time of dispensing to the patient; and

☐☐☐ The quantity of drugs dispensed to any patient pursuant to this section are limited to that amount necessary to maintain uninterrupted therapy during the period when pharmacy services outside the hospital are not readily available or accessible, but shall not exceed a 72-hour supply;

☐☐☐ The prescriber shall ensure that the label on the drug contains all the information required by Section 4076. (B&PC 4068[a][7])

☐☐☐ The prescriber shall be responsible for any error or omission related to the drugs dispensed. (B&PC 4068[b])

☐☐☐ The brand name or generic name and manufacturer of the prescription drug is accurately identified on the label an prescription record. (B&PC 4076, CCR 1717)

☐☐☐ Controlled substances are dispensed in prescription containers bearing a federal warning label prohibiting transfer of the drugs. (CFR 290.5)

Yes No N/A

☐☐☐ Prescriptions are dispensed in new, senior-adult ease –of-opening tested, and child-resistant containers or in a noncomplying package, only pursuant to the prescription or when requested by the purchaser. (15 USC 1473 section 4[b], 16 CFR 1700.15. CCR 1717)

☐☐☐ Patient package inserts are dispensed with all estrogen and progesterone medications (21 CFR 310.515, 310.516)

CORRECTIVE ACTION OR ACTION PLAN: _____

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21. Discharge Medication/Consultation Services

Yes No N/A

☐☐☐ Patients receive information regarding each medication given at the time of discharge. The information includes the use and storage of each medication, the precautions and relevant warnings and the importance of compliance with directions. A written policy has been developed in collaboration with a physician and surgeon, a pharmacist, and a registered nurse and approved by the medical staff that ensures that each patient receives the medication consultation. (B&PC 4074, CCR 1707.2)

☐☐☐ Prescriptions are transmitted to another pharmacy as required by law. (B&PC 4072, CCR 1717[f], 1717.4)

☐☐☐ The prescription label contains all the required information. (B&PC 4076)

☐☐☐ Appropriate drug warnings are provided orally or in writing. (B&PC 4074, CCR 1744)

☐☐☐ The trade name or generic name and manufacturer of the prescription drug is accurately identified on the label and prescription record. (B&PC 4076, CCR 1717)

☐☐☐ Generic substitution for discharge medications is communicated to the patient, and the name of the dispensed drug product is indicated on the prescription label. (B&PC 4073)

☐☐☐ If the prescription is filled by a pharmacy technician, the pharmacist's initials are on the prescription label to document the pharmacist's verification of the product. (B&PC 4115[f], CCR 1793.7)

☐☐☐ Controlled substances are dispensed in prescription containers bearing a federal warning label prohibiting transfer of the drugs. (21 CFR 290.5)

☐☐☐ Prescriptions are dispensed in a new and child-resistant container, or senior-adult ease-of-opening tested container, or in a non-complying package only pursuant to the prescriber or when requested by the purchaser. (25 USC 1473 section 4[b], 16 CFR 1700.15, CCR 1717)

☐☐☐ Patient package inserts are dispensed with all estrogen and progesterone medications. (21 CFR 310.515, 310.516)

CORRECTIVE ACTION OR ACTION PLAN: _____

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22. Central Fill

Yes No N/A

☐☐☐ Pharmacy processes orders for the filling of patient cassettes for another hospital or Pharmacy receives filled medication orders or patient cassettes from another hospital. (CCR 1710[b])

- If the answer is yes, name of hospital: _____

☐☐☐ Pharmacy receives filled medication containers or cassettes from another pharmacy. (CCR 1710[b])

- If the answer is "yes", name of supplying pharmacy: _____
- If the answer to this and the previous question is "no" or "not applicable" go to Section 23.

☐☐☐ Prescription information is electronically transferred between the two pharmacies (CCR 1710[b][6])

☐☐☐ Pharmacy has a contract with the ordering hospital pharmacy or has the same owner. (CCR 1710[b][1])

☐☐☐ Filled cassettes are delivered directly to the ordering hospital pharmacy. (CCR 1710[b][2])

☐☐☐ Each cassette or container meets the requirements of Business and Professions Code section 4076 (CCR 1710[b][3]

☐☐☐ Complete and accurate records are maintained of each cassette fill transaction, including the name of the pharmacist checking the cassettes at each pharmacy. (CCR 1710[b][5])

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

23. Policies and Procedures

There are written policies and procedures in place for:

Yes No N/A

☐☐☐ The assurance that each patient received information regarding each medication given at the time of discharge.

☐☐☐ Action to be taken to protect the public when a licensed individual employed by or with the pharmacy is known to be chemically, mentally, or physically impaired to the extent that it effects his or her ability to practice the profession or occupation authorized by his or her license; (B&PC 4104[a])

☐☐☐ Action to be taken to protect the public when a licensed individual employed by or with the pharmacy is known to have engaged in the theft or diversion or self-use of prescription drugs belonging to the pharmacy; (B&PC 4104[b])

Yes No N/A

☐☐☐ Oral consultation for discharge medications to an inpatient of a health care facility licensed pursuant to H&SC 1250, or to an inmate of an adult correctional facility or juvenile detention facility (B&PC 4074, CCR 1707.2[b][3]); and

☐☐☐ Operation of the pharmacy during the temporary absence of the pharmacist for breaks and meal periods including authorized duties of personnel, pharmacist's responsibilities for checking all work performed by ancillary staff, and pharmacist's responsibility for maintaining the security of the pharmacy. (CCR 1714.1[f])

☐☐☐ Assuring confidentiality of medical information if your pharmacy maintains the required dispensing information for prescriptions, other than controlled substances, in a shared common electronic file. (CCR1717.1[e])

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

24. Compounding Sterile Injectable Drugs

a. Compounding Area for Parenteral Solutions (if applicable)

Yes No N/A

☐☐☐ Pharmacy has a board issued Licensed Sterile Compounding permit or has current accreditation from the Joint Commission on Accreditation of Healthcare Organizations, or other board approved accreditation agency. (B&PC 4127.1(a) and 4127.1[d])

LSC Permit # _____ or

Name of accreditation agency _____

The pharmacy has a designated area or cleanroom for the preparation of sterile products that has the following:

☐☐☐ An ISO class 5 laminar airflow hood within an ISO class 7 cleanroom (B&PC 4127.7[a]);

☐☐☐ A positive air pressure differential in the cleanroom that is relative to adjacent areas (B&PC 4127.7[a]);

☐☐☐ An ISO class 5 cleanroom ((B&PC 4127.7[b]);

☐☐☐ A barrier isolator that provides an ISO class 5 environment for compounding ((B&PC 4127.7[c]); and

☐☐☐ The preparation of sterile injectable products is conducted in an environment that meets criteria specified in pharmacy's written policies and procedures. (CCR 1751.01[a])

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

b. Facility and Equipment Standards

Yes No N/A

☐☐☐ The compounding environment meets criteria specified in pharmacy's written policies and procedures for safe compounding of sterile injectable drugs. (CCR 1751.01[a])

☐☐☐ Only those who are properly attired (pursuant to ((CCR 1751.4) are allowed in the cleanroom. ((CCR 1751.01[b])

☐☐☐ All equipment used in the designated cleanroom is made of easily cleaned and disinfected material. (CCR 1751[c])

☐☐☐ Exterior workbench surfaces and other hard surfaces in the cleanroom, such as walls, floors,

could increase risk of contamination. (B&PC 1751.01[d])

☐☐☐ There are current and appropriate reference materials regarding the compounding of sterile injectable products located in or immediately available to the pharmacy. (CCR 1751.9)

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

c. Policies and Procedures

The pharmacy has written policies and procedures associated with the preparation and dispensing of sterile injectable products and includes: (CCR 1751.02)

Yes No N/A

☐☐☐ Compounding, filling, and labeling of sterile injectable compounds;

☐☐☐ Labeling of the sterile injectable product based on the intended route of administration and recommended rate of administration;

☐☐☐ Equipment and supplies;

☐☐☐ Training of staff in preparation of sterile injectable products;

☐☐☐ Training of patient and/or caregiver in the administration of compounded sterile injectable products;

☐☐☐ Procedures for the handling and disposal of cytotoxic agents;

☐☐☐ Quality assurance program; and

☐☐☐ Record keeping requirements.

☐☐☐ Ingredients and compounding process for each preparation is determined in writing and reviewed by a pharmacist before compounding begins. ((CCR 1751.02 [b])

If compounding sterile injectable products from one or more non-sterile ingredients, the pharmacy has written policies and procedures that comply with the following:

Yes No N/A

☐☐☐ Policies and procedures are immediately available to all compounding personnel and board inspectors (CCR 1751.02 [c][1]); and

☐☐☐ All compounding personnel have read the policies and procedures, any additions, revisions, and deletions before compounding. (CCR 1751.02 [c][2])

Policies and procedures address the following: (CCR 1751.02 [c][3] [A-K])

☐☐☐ Competency evaluation;

☐☐☐ Storage and handling of products and supplies;

☐☐☐ Storage and delivery of final products;

☐☐☐ Process validation;

☐☐☐ Personnel access and movement of materials into and near the controlled area;

☐☐☐ Use and maintenance of environmental control devices used to create the critical area for manipulation of sterile products (i.e., laminar-airflow workstations, biological safety cabinets, class 100 cleanrooms, and barrier isolator workstations;

☐☐☐ A regular cleaning schedule for the controlled area and any equipment in the controlled area and the alternation of disinfectants. Pharmacies subject to an institutional infection control policy may follow that policy as it relates to cleaning schedules;

☐☐☐ Disposal of packaging materials, used syringes, containers, and needles to enhance sanitation and avoid accumulation in the controlled area;

☐☐☐ For sterile batch compounding, written policies and procedures for the use of master formulas and work sheets and for appropriate documentation;

☐☐☐ Sterilization; and

☐☐☐ End-product evaluation and testing.

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

d. Labeling

The pharmacy's compounded sterile injectable product labels contain: (CCR 1751.2)

☐☐☐ Telephone number of the pharmacy, unless dispensed for a hospital in-patient;

Yes No N/A

☐☐☐ Name and concentrations of ingredients contained in the product;

☐☐☐ Instructions for storage and handling; and

☐☐☐ A special label which states “Chemotherapy—Dispose of Properly” for all cytotoxic agents.

CORRECTIVE ACTION OR ACTION PLAN: _____

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e. Record keeping Requirements

Yes No N/A

☐☐☐ Pharmacy records for sterile injectable products produced for future use (pursuant to section 1716.1), in addition to record requirements of section 1716.2, contain the name, lot number, amount, and date on which the products were provided to a prescriber. (CCR 1751.3[a])

☐☐☐ Records for sterile products compounded from one or more non-sterile ingredients are maintained for at least three years and contain the following: (CCR 1751.3[b])

☐☐☐ The training and competency evaluation of employees in sterile product procedures;

☐☐☐ Refrigerator and freezer temperatures;

☐☐☐ Certification of the sterile compounding environment;

☐☐☐ Other facility quality control logs specific to the pharmacy’s policies and procedures (e.g., cleaning logs for facilities and equipment);

☐☐☐ Inspection for expired or recalled pharmaceutical products or raw ingredients; and

☐☐☐ Preparation records including the master work sheet, the preparation work sheet, and records of end-product evaluation results.

☐☐☐ The pharmacy maintains records of validation processes as required by Section 1751.7(b) for three years. (CCR 1751.3[c])

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

f. Attire

Yes No N/A

☐☐☐ When preparing cytotoxic agents, gowns and gloves are worn. (CCR 1751.4[a])

When compounding sterile products from one or more non-sterile ingredients and a barrier isolator is <u>not</u> used:

Yes No N/A

☐☐☐ Cleanroom garb is donned and removed outside the designated area; (CCR 1751.4[b][2])

☐☐☐ Individuals in the cleanroom wear a low-shedding coverall, head cover, face mask, and shoe covers; (CCR 1751.4[b][1])

☐☐☐ No hand, finger, or wrist jewelry is worn or if the jewelry cannot be removed, it is cleaned and covered with a sterile glove; (CCR 1751.4[b][3])

☐☐☐ Head and facial hair is kept out of critical area or covered (CCR 1751.4[b][4]); and

☐☐☐ Gloves of low-shedding material are worn. (CCR 1751.4[b][5])

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

g. Training of Staff, Patient, and Caregiver

Yes No N/A

☐☐☐ Consultation is available to the patient and/or primary caregiver concerning proper use of sterile injectable products and related supplies furnished by the pharmacy. (CCR 1751.5[a])

☐☐☐ The pharmacist-in-charge ensures that all pharmacy personnel engaging in compounding sterile injectable drug products has training and demonstrated competence in the safe handling of those products, including cytotoxic agents if the pharmacy compounds such agents. (CCR 1751.5[b])

☐☐☐ Records of training and demonstrated competence are available for each individual and are retained for three years beyond the employment period. (CCR 1751.5[c])

☐☐☐ The pharmacist-in-charge ensures the continuing competence of pharmacy personnel engaged in compounding sterile injectable products. (CCR 1751.5[d])

☐☐☐ When compounding sterile products from one or more non-sterile ingredients, the pharmacy complies with the following training requirements: (CCR 1751.5[e])

☐☐☐ The pharmacy follows a written program of training and performance evaluation designed to ensure that each person working in the designated area has the knowledge and skills necessary to perform their assigned tasks properly. This program of training and performance evaluation addresses the following: (CCR 1751.5[e][1][A-J])

☐☐☐ Aseptic technique;

☐☐☐ Pharmaceutical calculations and terminology;

☐☐☐ Sterile product compounding documentation;

☐☐☐ Quality assurance procedures;

Yes No N/A

☐☐☐ Proper gowning and gloving technique;

☐☐☐ General conduct in the controlled area;

☐☐☐ Cleaning, sanitizing, and maintaining equipment used in the controlled area;

☐☐☐ Sterilization techniques; and

☐☐☐ Container, equipment, and closure system selection.

☐☐☐ Each person assigned to the controlled area successfully completes practical skills training in aseptic technique and aseptic area practices. (CCR 1751.5[e][2])

☐☐☐ Evaluation includes written testing and a written protocol of periodic routine performance checks involving adherence to aseptic area policies and procedures.

☐☐☐ Each person's proficiency and continuing training is reassessed every 12 months.

☐☐☐ Results of these assessments are documented and retained in the pharmacy for three years.

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

h. Disposal of Waste Material

Yes No N/A

☐☐☐ The pharmacy has written policies and procedures for the disposal of infectious material and/or materials containing cytotoxic residues. (CCR 1751.6)

☐☐☐ The procedures include the cleanup of spills and are in conformance with local health jurisdiction. (CCR 1751.6)

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

i. Quality Assurance and Process Validation

Yes No N/A

☐☐☐ There is a documented, ongoing quality assurance program that monitors personnel performance, equipment, and facilities, and the pharmacist-in-charge assures that the end product meets the required specifications by periodic sampling. (CCR 1751.7[a])

The Quality Assurance Program contains at least the following: (CCR 1751.7[a][1-5])

☐☐☐ Cleaning and sanitization of the parenteral medication preparation area;

Yes No N/A

☐☐☐ Batch produced sterile injectable drug products compounded from one or more non-sterile ingredients are subject to documented end product testing for sterility and pyrogens and are quarantined until the end product testing confirms sterility and acceptable levels of pyrogens;

☐☐☐ The storage of compounded sterile injectable products in the pharmacy and periodic documentation of refrigerator temperature;

☐☐☐ Steps to be taken in the event of a drug recall; and

☐☐☐ Written justification of the chosen expiration dates for compounded sterile injectable products in accordance with CCR 1716.2[a][3])

☐☐☐ Each individual involved in the preparation of sterile injectable products successfully completes a validation process on technique before being allowed to prepare sterile injectable products. (CCR 1751.7[b])

☐☐☐ The validation process is carried out in the same manner as normal production, except that an appropriate microbiological growth medium is used in place of the actual product used during sterile preparation. (CCR 1751.7[b])

☐☐☐ The validation process is representative of all types of manipulations, products and batch sizes the individual is expected to prepare. (CCR 1751.7[b])

☐☐☐ The same personnel, procedures, equipment, and materials are involved. (CCR 1751.7[b])

☐☐☐ Completed medium samples are incubated. (CCR 1751.7[b])

☐☐☐ If microbiological growth is detected, the sterile preparation process is evaluated, corrective action taken, and the validation process is repeated. (CCR 1751.7[b])

☐☐☐ Personnel competency is revalidated and documented at least every 12 months, whenever the quality assurance program yields an unacceptable result, when the compounding process changes, equipment used in the compounding of sterile injectable drug products is repaired or replaced, the facility is modified in a manner that affects airflow or traffic patterns, or whatever aseptic techniques are observed. (CCR 1751.7[b])

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

j. Reference Materials

Yes No N/A

☐☐☐ Current reference materials are maintained or available to the pharmacy on the drugs and chemicals used in parenteral therapy services and all parenteral therapy manufacturing, dispensing, distribution, and counseling services provided. (CCR 1751.9)

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

PHARMACIST-IN-CHARGE CERTIFICATION:

I, (please print) _____, RPH # _____ hereby certify that I have completed the self-assessment of this pharmacy of which I am the pharmacist-in-charge. I understand that all responses are subject to verification by the Board of Pharmacy. I further state under penalty of perjury that the information contained in this self-assessment form is true and correct.

Signature _____ Date _____
(Pharmacist-in-Charge)

Legal References used in the self-assessment forms (California Code of Regulations [CCR], Title 16 and Title 24, and Business and Professions Code [B&PC], Chapter 9, Division 2) can be found in the *California Pharmacy Law* (below) or visit the Board of Pharmacy Web site at www.pharmacy.ca.gov under *California Pharmacy Law and Index.*

The Health and Safety Code (H&SC), Division 10, Uniform Controlled Substances Act is also in the *California Pharmacy Law* (below) or you can visit the Board of Pharmacy Web site at www.pharmacy.ca.gov under *California Pharmacy Law and Index.*

California Code of Regulations (CCR), Chapter 1, Division 5, Title 22, and other references can be found in the California State Law Library or county law libraries.

Code of Federal Regulations (CFR), Title 21, Chapter II, Drug Enforcement Administration, may be found at www.dea.gov.

California Board of Pharmacy
1625 N. Market Blvd, Suite N219
Sacramento CA 95834
(916) 574-7900
fax: (916) 574-8618
www.pharmacy.ca.gov

California Pharmacy Law may be obtained by contacting:
Law Tech
1060 Calle Cordillera, Suite 105
San Clements CA 92673
(800) 498-0911 Ext. 74
www.lawtech-pub.com

Pharmacist Recovery Program
(800) 522-9198 (24 hours a day)

Atlantic Associates, Inc. (CURES)
Prescription Collection
8030 S. Willow Street, Bldg. III, Unit 3
Manchester NH 03103
(888) 492-7341

Medical Board of California
1426 Howe Avenue, Suite 54
Sacramento CA 95825
(800) 633-2322
(916) 263-2499
fax: (916) 263-2387
www.medbd.ca.gov

The **Drug Enforcement Administration** may be contacted at:

DEA – Los Angeles
255 East Temple Street, 20th Floor
Los Angeles, CA 90012
(213) 621-6942, or 6952 (Diversion & Investigations)

San Francisco
450 Golden Gate Avenue
San Francisco, CA 94102
(415) 436-7900 (DEA 106 registration)
(415) 436-7854 (Diversion & Investigations)

Sacramento
4328 Watt Avenue
Sacramento, CA 95821
(916) 480-7100 (Main Line Number)
(916) 480-7250 (Diversion & Investigations)

Riverside
4470 Olivewood Avenue
Riverside, CA 92501-69210
(909) 328-6000 (Main Line Number & Investigations)

Fresno
2444 Main Street, Suite 240
Fresno, CA 93721
(559) 487-5402 (Main Line Number & Investigations)

San Diego
4560 Viewridge Avenue
San Diego, CA 92123-1637
(858) 616-4100 (Main Line Number & Investigations)

Oakland
1301 Clay Street, Suite 460N
Oakland, CA 94612
(510) 637-5600 (Main Line Number)

San Jose
One North First Street, Suite 405
San Jose, CA 95113
(408) 291-7620 (Main Line Number)
(408) 291-2631 (Diversion & Investigations)

Redding
310 Hensted Drive, Suite 310
Redding, CA 96002
(530) 246-5043 (Main Line Number)

Santa Rosa*
5770 Skylane Boulevard
Windsor, CA 95492
(707) 565-5463 (Investigates Only **Illegal Drugs**)
***San Francisco office handles all Diversions & Investigations on Prescription Drugs at (415) 436-7854)**